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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/03/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,718

Applicant(s)

Dasseux et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 26, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 20-35, and 43-83 is/are pending in the application.
- 4a) Of the above, claim(s) 20-35, 43-55, and 76-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 56-75, and 79-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Status of Claims

Amendment filed 02/26/02 is acknowledged. Claims 2-9,12-19,36-42 are canceled. Claims 43-70 are added. However, as claims up to claim #55 are already of record, the new claims 43-70 are re-numbered as claims 56-83, respectively. Amendment of claims 58-64,69,73,75 to indicate proper base claim number is requested.

Further, in the list of pending claims, applicants do not recite claims 20-35,43-55 which remain pending but which had been withdrawn from further consideration in the previous Office action. Formal cancellation of claims 20-35,43-55 is requested.

Further restriction

Upon consideration of the newly submitted claims the following additional restriction was deemed necessary.

- I.1 Claims 1, 56-75,79-83 drawn to Apo-1 peptide agonists.
- I.3 Claims 76-78, drawn to peptide-lipid complexes.

Inventions I.1 and I.3 are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this

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relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as Apo-1 agonist on its own and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Additionally, the protein-lipid complexes of Group I.3 require non-coextensive search as a reference teaching a peptide of Group I.1 will not teach or suggest a peptide-lipid complex of Group I.3.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 76-78 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim Rejections - 35 U.S.C. § 112, second paragraph

Claims 56-75, 79-83 are rejected under 35 U.S.C. 112, second paragraph, because the phrase "a deleted peptide or peptide analogue" is not clear. Does the term "deleted" refer only to "peptide" or to "peptide and peptide analogue"? In the former case the following objection is applicable:

Claim Objections

Claims 1, 65, 67-75, 79-83 is objected as they still read on non-elected subject matter, i.e., full-length peptide as recited in claim 1(I). Note, that applicants elected deleted analogs of claim 1(ii). Amendment to the claim 1 to cancel non-elected subject matter is requested.

Claim Rejections - 35 U.S.C. § 112, first paragraph (new matter)

Claims 1, 57, 60, 61, 62, 63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 30, 34, 38 introduce new matter as they recite deletion of two helical turn. Specification, p. 51, lines 1-3, specifies that the number of deleted residues should be such that "one complete turn is deleted".

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Claims 64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 64 introduces new matter as it recites that residue 18 should not be deleted. No such limitation is present in the original specification - see p. 51, line 21.

Claim Rejections - 35 U.S.C. § 112, first paragraph (enablement)

Claims 1, 56-75, 79-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for full-length peptides of formula 1, does not reasonably provide enablement for any deletion analog of said peptides. The rejection is maintained for the reasons of record as applied to claims 1-13, 36-42 and in view of the following.

The claims are drawn to deletion analogs wherein any two helical turns can be deleted. The residues can be deleted at any random order. The only disclosed utility for the claimed peptides is being ApoA-1 agonists. The specification clearly describes on pages 25-46 that the peptides must conform to various structural requirements in order to display the expected utility. Deletion of a substantial, up to eight residues, portion of the peptide structure will inevitably alter both the structural and functional properties of peptide analogs. The amino acid sequence of the peptide is of great

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importance in determining the secondary and tertiary structures of the peptide. This is because the peptide's structure is determined by the interplay of the hydrophobic/hydrophilic, steric and electrostatic forces among the linked amino acid residues. Deleting a single residue alters these forces unpredictably and, consequently, may alter bioactivity unpredictably. The specification does not disclose a core structure required for the deletion analogs to maintain their biological activity. The only guidance in specification in regard to deletion analogs is related to number of residues required to delete a full turn of alpha helix. No guidance is present, however, is what core structure is required for a deletion analogue to retain its ability to be an ApoA-1 antagonist. Contrary, specification declares that helical turns can be removed from any randomly taken position in the chain; clearly such unspecified deletions of up to 8 residues will interfere with the ability of a peptide to interact with its target molecule, ApoA-1. It is noted that applicant refers to p. 51, lines 14-22, as showing preferred embodiments of deleted analogs. However, said part of specification does not show any operative embodiments and particular species having claimed biological activity; instead it merely informs that basic and acidic residues are essential to retain helical structure (as opposed to biological activity; the latter can not be attributed merely to spacial structure of a peptide but requires certain specific peptide sequence as well).

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Even in regard to deletions of helical turns, the specification is ambiguous. From one hand, the specification specifies that basic and acidic residues in positions 3,6,9,10,19,22 should not be removed. From the other hand, all claims allow random deletion of residues (claims 64,65 specify some, but not all residues that should not be removed). Further, in regard to the start and end position positions of a helical turn to be deleted, specification informs that this position depends upon the position of the first residue to be deleted (p. 51, line 8), rather than on the actual beginning of the turn. Further, it remains unclear how many residues, 3 or 4, should be deleted in a random deletion. The actual size of a helical turn is determined by the particular residues constituting this turn; thus, in each case, the number of the residues will be different and removal of an extra residue, e.g., 4 instead of 3, will perturb the following turn, while retaining a residue belonging to a deleted helical turn will deteriorate the whole helical structure of the peptide.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples in regard to deletion analogues, one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

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Double Patenting

The double-patenting rejection of record is maintained. Applicants submitted Terminal Disclaimer over U.S. Patent Nos. 6004925, 6037323, and 6265377. However, the Disclaimer was found to be defective as it lists more inventors (six) than are actually on the record (five). Submission of a substitute Disclaimer is requested.

Claims 1,57-76 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims of copending Application No. 09/453841. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

April 29, 2002

mlb

